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(54) **APPARATUS FOR ABLATION**
VORRICHTUNG ZUR ABLATION
APPAREIL D'ABLATION

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Description

This invention relates generally to the field of devices for cardiac surgery, and more specifically to devices for chemical ablation of cardiac tissue.

The present invention is directed toward treatment of tachyarrhythmias, which are heart rhythms in which a chamber or chamber of the heart exhibits an excessively fast rhythm. In particular, the present invention is directed toward treatment of tachycardias, which are due to the presence of ectopic foci within the cardiac tissue or due to the presence of aberrant condition pathways within the cardiac tissue.

Injection of alcohol into heart tissue has been employed to ablate cardiac tissue. Alcohol may be delivered to blood vessels supplying the tissue to be ablated, as described in "Transcoronary Chemical Ablation of Arrhythmias", by Nellens et al, Pace Vol. 15, pages 1368-1373, Sept. 1992. Alternatively, alcohol can be delivered directly to the tissue to be ablated by means of a needle inserted through a catheter, as described in "Chemical Ablation by Subendocardial Injection of Ethanol via Catheter - Preliminary Results in the Pig Heart", by Weismuller et al, European Heart Journal, Volume 12, pages 1234-1239, 1991.

According to the present invention, there is provided a catheter system, comprising:

an elongate catheter body having a proximal end, a distal end and an internal longitudinal lumen;
a hollow needle mounted to the proximal end of said catheter body and having an internal lumen coupled to the internal lumen of said catheter body; and
fluid delivery means coupled to the internal lumen of said catheter body for delivering a fluid under pressure to said internal lumen of said catheter body, characterised in that
said hollow needle is a helical needle.

The present invention is directed toward improving the consistency and efficacy of chemical ablation, and to increase the overall size and extent of the lesions induced by chemical ablation. These goals are pursued by means of an ablation catheter employing a helical needle intended to be screwed into the myocardium at the site intended for ablation. The helical needle serves to stabilize the location of the catheter during the application of the alcohol or other chemical ablation fluid. In addition, the helical shape of the needle prevents the application of alcohol through the needle from causing the needle to be backed out of its insertion site due to hydraulic pressure, as might occur if a straight, hollow needle were employed. The elongate path defined by the helical needle also reduces the possibility of leakage along the needle and out of the heart tissue. In addition, there is essentially no bleeding following removal of the helical needle, so it can safely be placed in multiple locations for mapping and ablation purposes.

The needle is electrically coupled to a connector on the proximal end of the catheter so that it may be employed for ECG monitoring or cardiac pacing. This feature allows the catheter to be employed to pre-test the identified ablation site by injection of an agent that reduces electrical excitability and thereafter monitoring the ECG via the needle to determine if the arrhythmia has been temporarily terminated. If so, injection of alcohol or other ablating agent follows to accomplish ablation. Otherwise, a new site may be located and pretested in the same fashion. Alternatively, the distance from the needle to the desired ablation site may be estimated by injecting known amounts of the excitability reducing agent and determining how much of the agent is required to temporarily terminate the arrhythmia. This information may be used to specify the dosage of alcohol or other ablating agent delivered or may assist in relocating the needle.

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings.

Figure 1 is a plan view of a catheter adapted to perform an improved method of R-F ablation, in accordance with the present invention.

Figure 2 is a cutaway view through the distal end of the catheter illustrated in Figure 1.

Figures 3 and 4 illustrate alternative embodiments of the helical electrode of the catheter illustrated in Figures 1 and 2.

Figure 5 illustrates the associated apparatus for administration of saline or Ringer's solution before and during application of R-F energy to the helical electrode.

Figure 1 is a plan view of a catheter specifically designed for performing chemical ablation according to the present invention. The catheter includes an elongate catheter body 10, comprising an insulative outer sheath 12, which may be made of polyurethane, Teflon®, or other biocompatible plastic. A hollow, helical needle 14 is located at the distal end of the catheter and is coupled to the distal end of an internal tube, running the length of the catheter. At the proximal end of the catheter a fitting 16 is located, to which luer lock 18 is coupled. Luer lock 18 is coupled to the proximal end of the internal tube. A swivel mount 20 is mounted to luer lock 18, allowing rotation of the catheter relative to luer lock 22. Luer lock 22 is intended to be coupled to a source of alcohol or other ablation fluid. An electrical connector 24 exits fitting 16, and is coupled to needle 14, allowing for the use of needle 14 for functions such as measurement of electrograms within the heart and pacing of heart tissue by application of low energy pulses appropriate for cardiac pacing.

In use, the catheter is advanced to the desired site for ablation, which may have been previously identified by means of cardiac mapping in a fashion similar to cardiac mapping presently employed with R-F ablation procedures. The catheter may be guided to the desired location by being passed down a steerable or guidable catheter, for example, as disclosed in U.S. Patent No.

5,030,204, issued to Badger et al., or by means of a fixed configuration guide catheter, for example in U.S. Patent No. 5,104,393, issued to Isner. Alternatively, the catheter may be advanced to the desired site within a heart by means of a deflectable stylet, as disclosed in PCT Patent Application Publication No. WO 93/04724, published March 18, 1993, or a deflectable guidewire as disclosed in U.S. Patent No. 5,060,660, issued to Gambale, et al. When the hollow needle 14 is located at the desired location it is screwed into heart tissue by rotating the catheter body. A torque cable within the catheter body provides for 1:1 torque transfer from the proximal end of the catheter to the hollow needle 14.

When advanced to the desired location, luer lock 22 may optionally be coupled to a pressurized source of an agent such as lidocaine or esmolol which reduces electrical excitability of the heart tissue. An appropriate injection apparatus is discussed in more detail in conjunction with Figure 6 below. The excitability reducing agent is delivered and the electrical connector is coupled to an ECG machine, allowing the effects of the anaesthetic on heart rhythm to be monitored. If the excitability reducing agent is effective to terminate the ectopic activity or interrupt the reentrant pathway associated with the arrhythmia, the site is determined to be appropriate for ablation. If not, the catheter may be relocated and the excitability reducing agent is injected into the new site.

Alternatively, the distance from the needle to the optimum ablation site may be estimated by injecting known amounts of the excitability reducing agent and determining how much of the agent is required to temporarily terminate the arrhythmia. The greater the amount of the agent required, the further the needle is from the optimum ablation site.

If the amount of the agent required to terminate the arrhythmia is less than a preset amount, alcohol or another ablation agent such as formaldehyde may be injected, in a dosage based upon the amount of the excitability reducing agent required. If the amount of excitability reducing agent required to terminate the arrhythmia is excessive, this information may still assist in relocating the needle in a subsequent attempt to identify an appropriate ablation site.

After the ablation site has been identified luer lock 22 is coupled to a source of pressurized alcohol. The alcohol is preferably delivered quickly, for example .5 cc of ethanol delivered in 4 seconds has been effective in animal testing. Again, the apparatus of Figure 5 may be employed to deliver the ablation fluid. During delivery of the ablation fluid, the proximal end of the catheter is held to prevent it from rotating, to maintain the hollow needle 14 in its desired location.

The helical configuration of needle 14 is believed to be particularly beneficial in the context of a chemical ablation catheter. Rapid injection of alcohol through a catheter as illustrated requires high pressure (e.g. 2758 kPa (400 psi) at the catheter entry point), and if a straight needle were to be employed , the possibility that the injected alcohol would act to push the needle out of the tissue hydraulically arises. Because the helical needle must be rotated out of tissue to be removed, and because the catheter includes a torque cable which prevents any substantial twisting of the catheter along its length, this problem can be avoided. Further, because the coiled needle is substantially longer than a corresponding straight needle inserted to the same depth, the injected fluid must travel along a longer path to escape the tissue by backflow along the needle. As noted above, the helical configuration of the needle also essentially eliminates bleeding at the insertion site.

After ablation, the needle 14 may be coupled to a cardiac pacemaker, and cardiac pacing energy may be delivered to the lesion site in an attempt to measure the pacing threshold. The inventors believe that the higher the pacing threshold, the higher local impedance, and, assuming a relatively homogenous lesion, the greater lesion size. As such, the needle 14 can be used to derive a rough estimate of overall lesion size. The needle 14 may also be coupled EKG monitoring equipment to assist in determining whether the tachycardia persists and whether the tissue in the vicinity of the electrode is still participating in aberrant conduction or ectopic activity, associated with the tachycardia.

Figure 2 illustrates a cutaway version through the end of the catheter illustrated in Figure 1. In this view, it can be seen that helical needle 14 is provided with an internal lumen 26 which is in communication with the internal lumen of a tube 30. Tube 30 extends to the proximal end of the catheter and is in full communication with luer lock 18, as discussed above, tube 30 may be fabricated of polyimide tubing or of stainless steel tubing. The stainless steel tubing serves as an additional conductor, coupling electrode 14 to electrical connector 24. The use of polyimide tubing, while reducing the overall conductivity of the catheter enhances the flexibility somewhat, and may be beneficial in some cases. In the event that polyimide tubing is employed, it is recommended to apply a steady flow of Ringer's solution through the polyimide tubing to electrode 14 during passage catheter through the vascular system to the ablation site, if possible. The flow of Ringer's solution in this case assists in maintaining the patency of the lumen of tubing 30, as the catheter is advanced through the bloodstream and also prevents plugging of the fluid exit ports on the needle as it enters the cardiac tissue. The apparatus of Figure 5 provides an appropriate mechanism for delivery if Ringer's solution if necessary.

Surrounding tube 30 are two coils 32 and 34, which are wound in opposite directions, to provide a torque cable. In the case of the specific devices employed by the inventors, a torque cable as manufactured by Lake Region Manufacturing Company of Chaska, Minnesota was employed, which torque cable is described in U.S. Patent No. 5,165,421. Coils 32 and 34 also serve as conductors. As illustrated, tubing 30 is between metal coils 32 and 34 and helical needle 14. However, if polyimide tubing is used, the coils 32 and 34 will serve as

the only conductor and thus will be electrically coupled to needle 14 by means of welding, soldering or mechanical interconnection. Insulative sleeve 12 serves both to provide a smooth exterior for the catheter and to insulate the metal coils 32 and 34, along the length of the catheter.

Figures 3 and 4 illustrate alternative embodiments of the helical needle illustrated in Figure 2. The needle 14 in Figure 2 comprises a hollow tube having a single exit port located as its distal end. Needle 36, illustrated in Figure 3, corresponds to needle 14 with the exception that additional exit ports 38, 40 and 42 have been added, allowing for dispensing of the alcohol along the length of the helix, to facilitate a wider distribution of alcohol and to increase the size of the lesion produced. Ports 38, 40 and 42 may be laser drilled, and may be spaced in any desired fashion around the circumference of needle 36 and along the length of needle 36. Preferably, it is believed desirable to have ports spaced around the full circumference of the needle, to provide for an even dispensing and dispersing of alcohol.

Needle 44, illustrated in Figure 4 is a second alternative embodiment of a helical needle corresponding to needle 14, but with the addition of an insulative sleeve 46, which covers the proximal portion of the electrode. Sleeve 46 limits the application of pacing pulses to the distal portion of the needle. Optionally, additional exit ports corresponding to ports 38, 40 and 42 illustrated in Figure 43 may also be employed in conjunction with needle 44. These additional exit ports may be limited to the exposed, uninsulated portion of needle 44, or may extend along the entire length of needle 44.

Figure 5 illustrates a pressurized source for alcohol, excitability reducing agent and Ringer's solution which may be employed in conjunction with catheter illustrated in Figure 1. Syringe 112 may be coupled to luer lock 22 by means of three way valve 110. Excitability reducing agent alcohol or other ablation fluid is simply placed in the syringe and delivered by injection. In the event that delivery of Ringer's solution is desired to maintain patency of the lumen of the inner tube, the illustrated apparatus also provides for this function. A reservoir 100 is provided, which is commercially manufactured by Block Medical, Inc., and sold under the brand name "Home Pump". The reservoir contains Ringer's solution and provides Ringer's solution at one atmosphere pressure to flow control 102, via filter 104. Flow control 102 may, for example, provide a flow limit of 20 drops or 1 cc per minute. Flow control 102 is coupled to a second flow control element 104, which, in the experimental apparatus employed by the inventors allows for additional adjustability of flow rates. Flow control 104 may be coupled to the luer lock 22 by means of three way valve 110. All other labelled elements correspond to those illustrated in Figure 1.

While the embodiment illustrated above requires a second element (e.g. a guide catheter or guide wire) for advancing and positioning the catheter at its desired location, it is anticipated that the basic apparatus disclosed above may also be incorporated into catheters which themselves are steerable or deflectable, similar to R-F ablation catheters presently in clinical investigation. Similarly, it is anticipated that in commercial embodiments, alternative mechanisms (e.g. precision pumps) for controlling the flow of anaesthetic, alcohol or Ringer's solution may be employed. Similarly, while the inventors have employed alcohol as an ablation solution, other alternative fluids (e.g. formaldehyde) may be workable as well. As such, the embodiment discussed above should be considered exemplary, rather than limiting, in conjunction with the following claims.

Claims

1. A catheter system, comprising:

   an elongate catheter body (10) having a proximal end, a distal end and an internal longitudinal lumen;
   a hollow needle (14) mounted to the proximal end of said catheter body (10) and having an internal lumen coupled to the internal lumen of said catheter body; and
   fluid delivery means coupled to the internal lumen of said catheter body for delivering a fluid under pressure to said internal lumen of said catheter body, characterised in that
   said hollow needle is a helical needle.

2. A catheter system according to claim 1, wherein said fluid delivery means comprises means for delivering an ablation fluid.

3. A catheter system according to claim 1 or 2, wherein said fluid delivery means comprises a reservoir (100) containing an excitability reducing agent and means (112) for delivering said excitability reducing agent under pressure to said internal lumen of said catheter body.

4. A catheter system according to claim 2 wherein said ablation fluid delivery means comprises means for delivering alcohol.

5. A catheter system according to claim 3 wherein said fluid delivery means comprises means for delivering lidocaine.

6. A catheter system according to claim 3 wherein said fluid delivery means comprises means for delivering esmolol.

7. A catheter system according to claim 1, wherein said fluid delivery means comprises means for delivering Ringer's solution.

8. A catheter system according to any preceding claim, wherein said fluid delivery means comprises

a syringe (112).

9. A catheter system according to any preceding claim, wherein said catheter body (10) comprises a torque transfer cable, extending longitudinally along said catheter body.

10. A catheter system according to any preceding claim, wherein said hollow needle (14) is conductive, wherein said catheter body (10) comprises a longitudinally extending electrical conductor coupled to said hollow needle, and further comprising an electrical connector mounted to said catheter body and coupled to said electrical conductor.

11. A catheter system according to claim 10 wherein said catheter body (10) comprises a conductive torque transfer cable, extending longitudinally along said catheter body, coupled to said hollow needle and to said electrical connector.

12. A catheter system according to claim 10 wherein said catheter body comprises a conductive tube, extending longitudinally along said catheter body, coupled to said hollow needle and to said electrical connector.

13. A catheter system according to claim 2 wherein said catheter body comprises a plastic tube, extending longitudinally along said catheter body, coupled to said hollow needle and to said ablation fluid delivery means.

Patentansprüche

1. Kathetersystem mit

einem langgestreckten Katheterhauptteil (10) mit einem proximalen und einem distalen Ende und einem inneren, sich in Längsrichtung erstreckenden Hohlraum,
einer am proximalen Ende des Katheterhauptteils (10) angebrachten Hohlnadel (14), die einen inneren Hohlraum, der mit dem des Katheterhauptteils in Verbindung steht, aufweist, und mit
einer mit dem inneren Hohlraum des Katheterhauptteils in Verbindung stehenden Fluidversorgungseinrichtung, durch die ein Fluid unter Druck dem inneren Hohlraum des Katheterhauptteils zugeleitet wird,
dadurch **gekennzeichnet**, daß
die Hohlnadel eine Spiralnadel ist.

2. Kathetersystem nach Anspruch 1, dadurch gekennzeichnet, daß die Fluidversorgungseinrichtung eine Einrichtung zum Zuführen eines Ablationsfluids umfaßt.

3. Kathetersystem nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Fluidversorgungseinrichtung einen ein die Erregung herabsetzendes Mittel enthaltenden Vorratsbehälter (100) und eine Einrichtung (112) zur Zuleitung des die Erregung vermindernden Mittels unter Druck zum inneren Hohlraum des Katheterhauptteils aufweist.

4. Kathetersystem nach Anspruch 2, dadurch gekennzeichnet, daß die Zufuhreinrichtung für das Ablationsfluid eine Einrichtung zur Zuführung von Alkohol umfaßt.

5. Kathetersystem nach Anspruch 3, dadurch gekennzeichnet, daß die Fluidversorgungseinrichtung eine Einrichtung zur Versorgung mit Lidocain umfaßt.

6. Kathetersystem nach Anspruch 3, dadurch gekennzeichnet, daß die Fluidversorgungseinrichtung eine Einrichtung zur Versorgung mit Esmolol umfaßt.

7. Kathetersystem nach Anspruch 1, dadurch gekennzeichnet, daß die Fluidversorgungseinrichtung eine Einrichtung zur Versorgung mit Ringer-Lösung umfaßt.

8. Kathetersystem nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Fluidversorgungseinrichtung eine Spritze (112) aufweist.

9. Kathetersystem nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Katheterhauptteil (10) eine Drehmomentübertragungsleitung aufweist, die sich in Längsrichtung entlang dem Katheterhauptteil erstreckt.

10. Kathetersystem nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Hohlnadel (14) leitfähig ist, und daß der Katheterhauptteil (10) einen sich in Längsrichtung erstreckenden, mit der Hohlnadel verbundenen elektrischen Leiter enthält sowie einen am Katheterhauptteil angebrachten und mit dem elektrischen Leiter verbundenen elektrischen Anschluß aufweist.

11. Kathetersystem nach Anspruch 10, dadurch gekennzeichnet, daß der Katheterhauptteil (10) eine leitfähige Drehmomentübertragungsleitung aufweist, die sich in Längsrichtung entlang des Katheterhauptteils erstreckt, und die mit der Hohlnadel und dem elektrischen Anschluß verbunden ist.

12. Kathetersystem nach Anspruch 10, dadurch gekennzeichnet, daß der Katheterhauptteil ein leitfähiges Rohr enthält, das sich in Längsrichtung entlang des Katheterhauptteils erstreckt und das mit der Hohlnadel und dem elektrischen Anschluß ver-

bunden ist.

13. Kathetersystem nach Anspruch 2, dadurch gekennzeichnet, daß der Katheterhauptteil ein Plastikrohr aufweist, das sich in Längsrichtung entlang des Katheterhauptteils erstreckt und das mit der Hohlnadel und der Zufuhreinrichtung für das Ablationsfluid verbunden ist.

Revendications

1. Système de cathéter comprenant :

   un corps de cathéter allongé (10) ayant un extrémité proximale, un extrémité distale et une lumière longitudinale intérieure ;
   une aiguille creuse (14) montée à l'extrémité proximale dudit corps de cathéter (10) et ayant une lumière intérieure reliée à la lumière intérieure dudit corps de cathéter ; et
   des moyens débiteurs de fluide reliés à la lumière intérieure dudit corps de cathéter pour débiter un fluide sous pression dans ladite lumière intérieure dudit corps de cathéter, caractérisé en ce que
   ladite aiguille creuse est une aiguille hélicoïdale.

2. Système de cathéter selon la revendication 1, dans lequel lesdits moyens débiteurs de fluide comprennent des moyens pour administrer un fluide d'ablation.

3. Système de cathéter selon la revendication 1 ou 2, dans lequel lesdits moyens débiteurs de fluide comprennent un réservoir (100) qui contient un agent réducteur d'excitabilité et des moyens (112) pour débiter ledit agent réducteur d'excitabilité sous pression à ladite lumière intérieure dudit corps de cathéter.

4. Système de cathéter selon la revendication 2, dans lequel lesdits moyens débiteurs de fluide d'ablation comprennent des moyens pour débiter de l'alcool.

5. Système de cathéter selon la revendication 3, dans lequel lesdits moyens débiteurs de fluide comprennent des moyens pour débiter de la lidocaïne.

6. Système de cathéter selon la revendication 3, dans lequel lesdits moyens débiteurs de fluide comprennent des moyens pour débiter de l'esmolol.

7. Système de cathéter selon la revendication 1, dans lequel lesdits moyens débiteurs de fluide comprennent des moyens pour débiter une solution de Ringer.

8. Système de cathéter selon une quelconque des revendications précédentes, dans lequel lesdits moyens débiteurs de fluide comprennent une seringue (112).

9. Système de cathéter selon une quelconque des revendications précédentes, dans lequel ledit corps de cathéter (10) comprend un câble de transfert de couple, qui s'étend longitudinalement le long dudit corps de cathéter.

10. Système de cathéter selon une quelconque des revendications précédentes, dans lequel ladite aiguille creuse (14) est conductrice, dans lequel ledit corps de cathéter (10) comprend un conducteur électrique s'étendant longitudinalement relié à ladite aiguille creuse et comprenant en outre un conducteur électrique monté sur ledit corps de cathéter et relié audit conducteur électrique.

11. Système de cathéter selon la revendication 10, dans lequel ledit corps de cathéter (10) comprend un câble de transfert de couple conducteur, qui s'étend longitudinalement le long dudit corps de cathéter, relié à ladite aiguille creuse et audit connecteur électrique.

12. Système de cathéter selon la revendication 10, dans lequel ledit corps de cathéter comprend un tube conducteur qui s'étend longitudinalement le long dudit corps de cathéter, relié à ladite aiguille creuse et audit connecteur électrique.

13. Système de cathéter selon la revendication 2, dans lequel ledit corps de cathéter comprend un tube en matière plastique, qui s'étend longitudinalement le long dudit corps de cathéter, relié à ladite aiguille creuse et auxdits moyens débiteurs de fluide d'ablation.

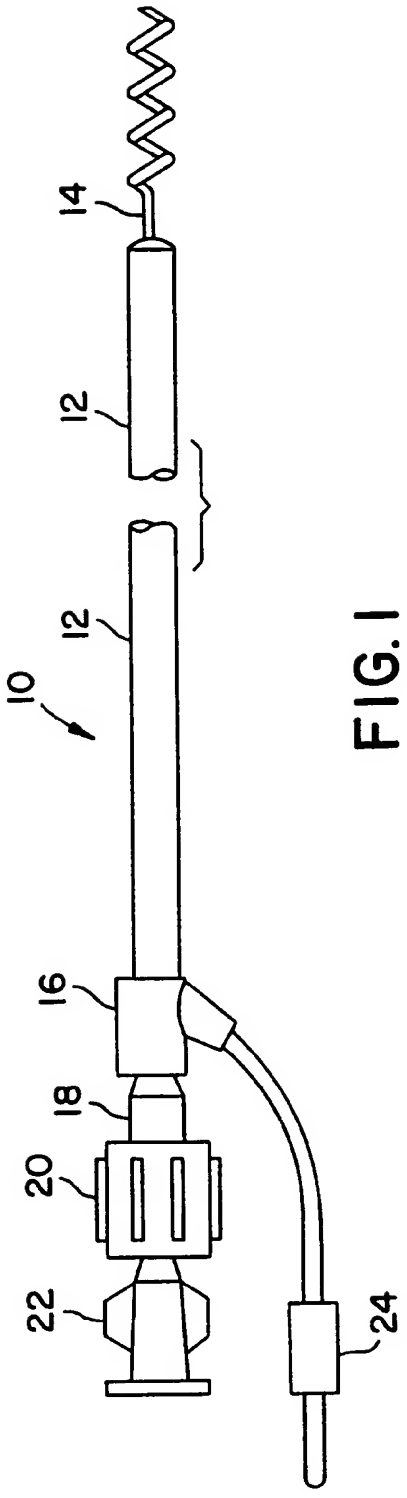

FIG. 1

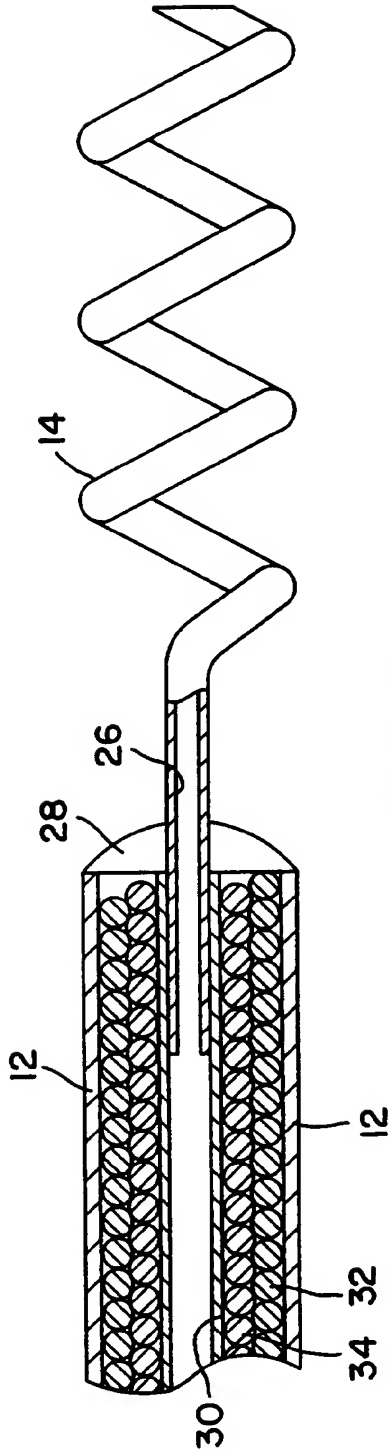

FIG. 2

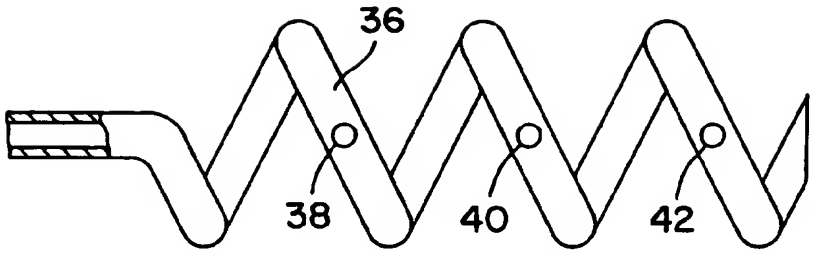

FIG. 3

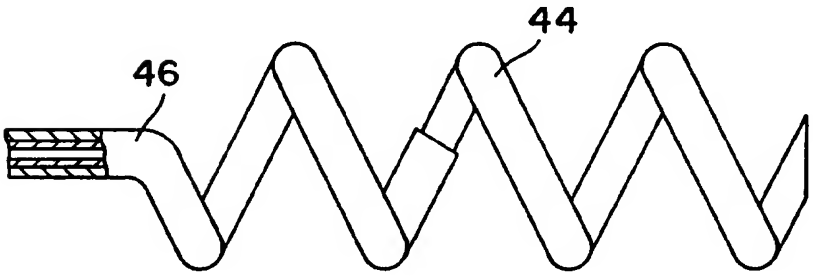

FIG. 4

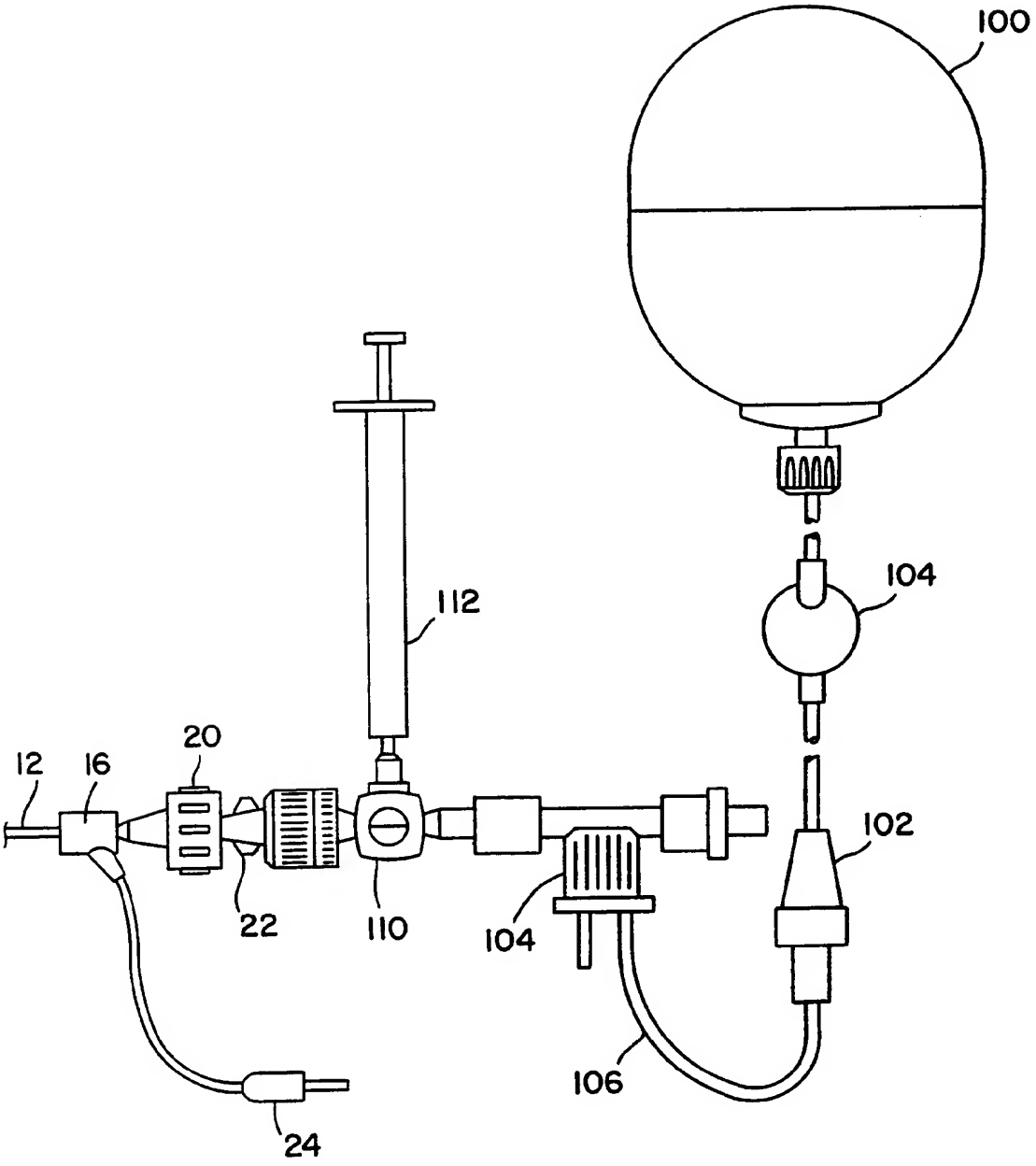

FIG. 5